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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/525,255	02/23/2005	Nachiket Kharalkar	622-0002US1	3631

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EXAMINER	
JONES, DAMERON LEVEST	

ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
06/29/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/525,255	KHARALKAR ET AL.	
	Examiner	Art Unit	
	D L. Jones	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 April 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5,6,9-12,14,15 and 23-29* is/are pending in the application.

4a) Of the above claim(s) *23-29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5, 6, 9-12, 14, and 15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of the amendment filed 4/16/10 wherein the specification was amended; claims 1-4, 7, 8, 13, and 16-22 were canceled; and claims 23-29 were added.

Note: Claims 5, 6, 9-12, 14, 15, and 23-29 are pending.

RESPONSE TO APPLICANT'S AMENDMENT/ARGUMENTS

2. The Applicant's arguments and/or amendment filed 4/16/10 to the rejection of claims 5, 6, 9-12, 14, and 15 made by the Examiner under 35 USC 103, 112, and/or double patenting have been fully considered and deemed non-persuasive for the reasons of record in the office action mailed 10/16/09 and those set forth below.

Double Patenting Rejections

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The provisional rejection of claims 1-22 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-20 of copending Application No. 11/871,901 is MAINTAINED. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to assessing some type of endothelial function by providing a vasodilating stimulant to a subject and monitor a change in hemodynamic activity. The claims differ in that those of the copending application are specifically for assessing vascular function. However, a skilled artisan using any medical dictionary would recognize that the term 'endothelial' may be defined as a layer of flat cells lining vessels such as blood and lymphatic vessels and the heart. Thus, the instant invention encompass that of the copending application. Hence, the inventions disclose overlapping subject matter..

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's Assertions

In summary, Applicant asserts that the instant invention precedes the invention of the copending application and that the later filed copending application is not a reference against the instant invention.

Examiner's Response

While the copending application may precede the instant invention, since the inventions contain overlapping subject matter, a double patenting rejection is proper. However, according to MPEP 804, the following actions by the Examiner will occur when a non-statutory provisional rejections is/are the only rejection(s) remaining in the application:

(a) If a "provisional" nonstatutory obviousness-type double patenting (ODP) rejection is the only rejection remaining in the earlier filed of the two pending applications, while the later-filed application is rejectable on other grounds, the examiner should withdraw that rejection and permit the earlier-filed application to issue as a patent without a terminal disclaimer. If the ODP rejection is the only rejection remaining in the later-filed application, while the earlier-filed application is rejectable on other grounds, a terminal disclaimer must be required in the later-filed application before the rejection can be withdrawn; OR

(b) If "provisional" ODP rejections in two applications are the only rejections remaining in those applications, the examiner should withdraw the ODP rejection in the

earlier filed application thereby permitting that application to issue without need of a terminal disclaimer. A terminal disclaimer must be required in the later-filed application before the ODP rejection can be withdrawn and the application permitted to issue. If both applications are filed on the same day, the examiner should determine which application claims the base invention and which application claims the improvement (added limitations). The ODP rejection in the base application can be withdrawn without a terminal disclaimer, while the ODP rejection in the improvement application cannot be withdrawn without a terminal disclaimer.

Thus, since other rejections are still of record, the ODP rejection is MAINTAINED.

Written Description Rejection

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 5, 6, 9-12, 14, and 15 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is MAINTAINED. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is reminded that an Inventor is entitled to a patent to protect his work only if he/she produces or has possession of something truly new and novel. The

invention being claimed must be sufficiently concrete so that it can be described for the world to appreciate the specific nature of the work that sets it apart from what was before. The Inventor must be able to describe the item to be patented with such clarity that the Reader is assured that the Inventor actually has possession and knowledge of the unique composition that makes it worthy of patent protection. The instant application does not sufficiently describe the invention as it relates to vasodilating stimulants. For example, in the art, it is known that vasodilation affects various relationships such as that between mean arterial pressure, cardiac output, and total peripheral resistance (TPR). In addition, vasodilators fall within three major classes including calcium channel blockers, cAMP mediated compounds, and cGMP mediated compounds. Possible endogenous vasodilators include EDHF, interstitial potassium, nitric oxide, beta-2 adrenergic agonists, histamine, prostacyclin, Prostaglandin D2, Prostaglandin E2, VIP, adenosine, arginine, bradykinin, Substance P, niacin, platelet activating factor, carbon dioxide, and interstitial lactic acid. Possible exogenous vasodilators include alpha blockers, amyl nitrite, atrial natriuretic peptide, ethanol, histamine inducers, nitric oxide inducers, tetrahydrocannabinol, theobromine, papaverine, and so forth. However, review of the instant specification sets forth that the vasodilator stimulant in the instant invention is directed to compression of a body part (i.e., compressing one of the arteries in an extremity such as the art (see US 2006/0165596, page 1, paragraph [0018] and page 2, paragraph [0025]). What the Reader gathers from the instant application is a desire/plan/first step for obtaining a desired result. While the Reader can certainly appreciate the desire for achieving a

certain end result, establishing goals does not necessarily mean that an invention has been adequately described.

While compliance with the written description requirements must be determined on a case-by-case basis, the real issue here is simply whether an adequate description is necessary to practice an invention described only in terms of its function and/or based on a disclosure wherein a description of the components necessary in order for the invention to function are lacking. In order to satisfy the written description requirement, the specification must describe every element of the claimed invention in sufficient detail so that one of ordinary skill in the art would recognize that the Inventor possessed the claimed invention at the time of filing. In other words, the specification should describe an invention and does so in sufficient detail that one skilled in the art can clearly conclude that the Inventor created what is the claimed. Thus, the written description requirement is lacking in the instant invention since the various terms as set forth above are not described in a manner to clearly allow persons of ordinary skill in the art to recognize that Applicant invented what is being claimed.

Applicant's Assertions

In summary, Applicant asserts that the new claims clearly describe the invention to a person skilled in the technology or profession as it relates to vasodilating stimulants. Applicant's arguments specifically refer to newly added claims 23-29.

Examiner's Response

First, it should be noted that claims 5, 6, 9-12, 14, 15, and 23-29 are pending. Secondly, it should be noted that claims 23-29 are withdrawn from consideration as set

forth above. Third, claims 5, 6, 9-12, 14, and 15 all in some way relate to a vasodilating stimulant(s) that range from calcium channel blockers, cAMP mediated compounds, and cGMP medicated compounds. Furthermore, review of the instant specification sets forth that the vasodilator stimulant in the instant invention is directed to a compression of a body part, not just any vasodilator stimulant as encompassed by the claims. Thus, the rejection is deemed proper.

112 Second Paragraph Rejections

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claims 5, 6, 9-12, 14, and 15 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is MAINTAINED.

The claims as written are ambiguous because one cannot ascertain what particular vasodilator stimulants Applicant is claiming that are compatible with the instant invention.

Applicant's Assertions

In summary, Applicant asserts that the rejection should be withdrawn because the claims over which the rejection was made are canceled. In addition, it is asserts that in regards to the Examiner's restriction requirement, the elected species wherein the vasodilator is occlusion of blood flow is not ambiguous.

Examiner's Response

First, Applicant is reminded that the claims are not limited to the elected species. Secondly, all of the previously pending claims have not been canceled and are thus, still indefinite. Furthermore, Applicant's reference to independent claim 23 as not being indefinite is correction; however, claims 23-29 are withdrawn from consideration.

103 Rejection

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The rejection of claims 5, 6, 9-12, 14, and 15 under 35 U.S.C. 103(a) as being unpatentable over Drzewiecki et al (US Patent No. 6,338,719) in view of Goor et al (US Patent No. 6,319,205) is MAINTAINED.

Drzewiecki et al disclose a method and system for assessing vascular and endothelial function of a subject using an arm cuff plethysmograph. The system may be configured with a computer to calculate/analyze brachial artery, lumen area, and pressure data (see entire document, especially, abstract; Figures 1-10; column 2, lines 7-16; columns 2-3, bridging paragraph; columns 3-4, bridging paragraph; column 4, lines 24-28; column 10, lines 23-46). The method of Drzewiecki et al enables one to measure the arterial volume as well as the blood flow (column 2, lines 17-54). However, Drzewiecki et al fail to disclose other means (i.e., using a finger probe) of assessing endothelial function and analyzing the data (i.e., Doppler effect or temperature).

Goor et al disclose a method and apparatus for monitoring arterial effects in subjects. The apparatus includes a contiguous pressure cuff and a finger probe in the form of a tube which is designed to apply press (see entire document, especially, abstract; Figures 1-11 and 23-27; column 9, lines 1-9; columns 11-12, bridging paragraph; columns 20-21, bridging paragraph; column 27, lines 23-26). In addition, Goor et al disclose that the prior art utilizes a photoplethysmograph that consist of a light transmitter and receiver placed on opposite sides of the finger tip (column 8, lines

7-13). The monitoring of Peripheral arterial tone may be detected by monitoring changes in various hemodynamic parameters such as blood flow, blood volume, the shape of the arterial pulse wave, the peripheral arteries, and so forth. The changes in blood may be determined by plethysmography of one or more parameters. Also, Goor et al disclose that the finger is and advantageous site for monitoring hemodynamic parameters because of its easy access (column 8, lines 54-67). Heating elements may be optionally added to the system to modify the degree of vascular tone (column 17, lines 60-67). Various means exist for determining arterial tone. Optical density or surface reflectivity of the outer end of the finger (or toe) or skin in other areas of the body may be measured using a light source and light collector. Electrical resistivity may be measured to determine the galvanic skin response. Blood velocity flow may be measured by a Doppler ultrasound device, laser Doppler device, or other flow meter devices (columns 20-21, bridging paragraph).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to assess endothelial function by providing a vasodilating stimulating and monitoring a hemodynamic parameter because like the instant invention, the cited prior art discloses a method and system for assessing arterial and endothelial function. The cited prior art involves the use of an occlusive arm cuff plethysmograph to monitor the data. Thus, both Applicant and the cited prior art disclose over lapping subject matter. Furthermore, it would have been obvious to modify the teachings of Drzewiecki et al using the teachings of Goor et al and monitor endothelial function in other ways such as by using a finger probe since Goor et al, like

Drzewiecki et al, disclose method and apparatus for assessing endothelial function by apply a compression to a desired area of the body. In addition, Goor et al disclose that the data may be analyzed using Doppler techniques. It would be obvious to monitor temperature changes since Goor et al disclose that a heating element may be present in combination with a thermistor and temperature controller. Also, Goor et al, like Drzewiecki et al, disclose the use plethysmography techniques for determining various parameters when assessing physiological function. Hence, the references may be considered to be within the same field of endeavor and thus the reference teachings are combinable.

Applicant's Assertions

In summary, Applicant asserts that the claims over which the rejection was made have been canceled. In addition, Applicant asserts that the cited prior art rejection is not applicable to the elected species. Also, Applicant asserts that neither Drzewiecki et al nor Goor et al contain a component for measuring temperature. Furthermore, it is asserted that a reference to optionally adding heat to a glove is not equivalent to monitoring temperatures. Applicant also asserts that in the instant invention a plethysmograph, an instrument for measuring volume, is not employed since Applicant is not monitoring volume.

Examiner's Response

First, Applicant is reminded that the claims are not limited to the elected species. Secondly, review of the pending claims (see pending claim 14) indicates that monitoring is accomplished by taking measurements with a photoplethysmograph. In Goor et al,

column 8, lines 62-65, disclose that the amount of blood may be determined by plethysmography of one or more parameters such as the finger's volume or optical density. Furthermore, in column 8, lines 7-9, it is disclosed that photoplethysmograph which consist of a light transmitter and a receiver placed on opposite sides of the finger tip, may be used to record light transmission changes in the finger. Thus, a skilled artisan would recognize that both the prior art and Applicant utilize a plethysmography. Likewise, Drzewiecki et al disclose that the detection of various vascular conditions may be determined using a plethysmograph (see entire document, especially abstract). Hence, both cited prior art documents disclose the use of a plethysmograph.

In Goor et al, column 26, lines, 26-31, for example, it is disclosed that the temperature of the finger device is monitored by a controller (component 17) connected to a thermistor (component 9) via electrical wires (component 18). Thus, the prior art does disclose a means by which temperature may be monitored.

In light of the response above, the rejection of record is deemed proper.

NEW GROUNDS OF REJECTIONS

112 Second Paragraph Rejections

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 5, 6, 9, 14, and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims as written are ambiguous because they depend on canceled claims. Specifically, claims 5, 6, and 9 depend on canceled claims 1 and claims 14 and 15 depend on canceled claim 13.

COMMENTS/NOTES

5. Applicant's attention is directed to the fact that the status of some of the claims is incorrect. Applicant is respectfully requested to make the appropriate corrections. In particular, claims 5, 6, 9-12, 14, and 15 are not 'withdrawn', but 'previously presented'. It should be noted that in the claims were examined in the office action mailed 10/16/09.

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D L. Jones whose telephone number is (571)272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D L. Jones/
Primary Examiner
Art Unit 1618

June 23, 2010